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Award Number: W81XWH-06-1-0194

TITLE: Prostate Cancer Survivors with Rising PSA and Their Spouses: Treatment Decision Making and Quality of Life

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REPORT DATE: December 2006

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-12-2006	Annual	01 Dec 05 – 30 Nov 06

4. TITLE AND SUBTITLE
Prostate Cancer Survivors with Rising PSA and Their Spouses: Treatment Decision Making and Quality of Life

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-06-1-0194

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Mount Sinai School of Medicine
New York NY 10029-6574

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This study involves patients and their spouses/partners who are attending two cancer centers: the Deane Prostate Health and Research Center in the Department of Urology at Mount Sinai Hospital, New York City and the Department of Medical Oncology at Fox Chase Cancer Center, Philadelphia. Patients will have been diagnosed with rising PSA but have no clinical evidence of cancer. Eligible patients and their spouse/partners who have agreed to participate (n = 191) will take part in a 12-months long assessment study. During this time, they will be interviewed via questionnaires four times: at the beginning (baseline), at 6-months, at 12-months and when they have made a treatment decision. Our research focus and the measures used for data collection are guided by our cognitive-social health information processing (C-SHIP) theoretical framework. This framework incorporates individuals' experiences, expectations, beliefs, values, and emotional responses to a health threat, and sees these components as influential factors in treatment decision making. Both the patient and the spouse/partner will be assessed. Due to the limited patient enrollment, no significant findings can be reported at this time.

15. SUBJECT TERMS
Prostate Cancer, Rising PSA, Treatment Decision Making, Quality of Life.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	7	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Abstract

This study involves patients and their spouses/partners who are attending two cancer centers: the Deane Prostate Health and Research Center in the Department of Urology at Mount Sinai Hospital, New York City and the Department of Medical Oncology at Fox Chase Cancer Center, Philadelphia. Patients will have been diagnosed with rising PSA but have no clinical evidence of cancer. Eligible patients and their spouse/partners who have agreed to participate (n = 191) will take part in a 12-months long assessment study. During this time, they will be interviewed via questionnaires four times: at the beginning (baseline), at 6-months, at 12-months and when they have made a treatment decision. Our research focus and the measures used for data collection are guided by our cognitive-social health information processing (C-SHIP) theoretical framework. This framework incorporates individuals' experiences, expectations, beliefs, values, and emotional responses to a health threat, and sees these components as influential factors in treatment decision making. Patients' interview schedule is linked conveniently to routine clinic visits to assess PSA levels. In addition, we will contact patients via telephone at 3 months, and 9 months to inquire whether they have made a treatment decision. When patients have made a decision, we will ask both the patient and the spouse/partner to complete an in-depth questionnaire about the decision making process and any difficulties they might have had making the decision. Data collection after a decision has been made will focus on physical symptoms and regret about the decision as well as the continued assessment of quality of life. Both patients and spouse/partners will be assessed.

Introduction. Advances in the treatment of prostate cancer have produced excellent 5-year survival chances. Despite this success, a growing number of patients experience a rise in prostate specific antigen (PSA) levels after treatment. Even if widespread disease is not found, a rising PSA is a sign that prostate cancer might have recurred. Recent estimates indicate that approximately 40% of patients who were initially treated with surgery or radiation therapy will experience a rise in PSA, yielding approximately 60,000 cases per year.

From a psychological point of view, patients and their spouses/partners are forced to deal with a disease they believed they have overcome. For a second time they face a health decision with few treatment guidelines, uncertain outcomes, and the potential for substantial side-effects. In addition, patients and their spouse/partners have to deal with the uncertainty of a cancer recurrence and cancer spread, and the possibility of death. Very little information exists in the literature how patients and their spouse partners make treatment decisions about a rising PSA and how both of their physical and emotional quality of life is changed by this condition. This application is designed to address this gap in the psycho-social management of prostate cancer.

Body: The first several months were spent obtaining regulatory clearance from both Mount Sinai School of Medicine (MSSM) and Fox Chase Cancer Center (FCCC), our second study site. Final IRB approval for both sites was obtained in Jan 19 2006 for MSSM and Jan 17 2006 for FCCC.

Mount Sinai Site: During the approval process we have created the SPSS data bases for data entry. The current database tracks both male and female study participants from both study sites, Mount Sinai and Fox Chase Cancer Center. Next, we modified, updated and expanded the focus group guide together with our collaborators at FCCC.

We have held several meetings with the collaborating physicians at MSSM to discuss recruitment procedures. Training of personnel was conducted in month 4 and several mock interviews were conducted under the supervision of the PI in month 5. To raise awareness of this research project we met with MSSM's public relation office and have the study listed on MSSM's clinical trials web-page. Furthermore, Dr. Diefenbach, in his continued outreach to the community talked about this ongoing research project with local support groups, such as the "Man to Man" group.

Fox Chase site: The PI visited FCCC several times to discuss recruitment procedures. Recruitment has been slow at FCCC for two reasons. First, the health educator who had been involved with the project through the submission and pilot testing phase left FCCC in April 2006 to pursue a graduate education in Public Health. Hiring and training a new health educator took approximately 3 months. After the new health educator was hired and trained a meeting was convened with the collaborating physicians and nurses at FCCC to clarify the recruitment procedures. Second, time was spent coordinating with several departments (Surgical, Radiation, and Medical Oncology) to organize and finalize recruitment efforts for the study. Meetings were set-up with several nurses and physicians regarding: 1) reviewing eligibility criteria, 2) methods on how study personnel could identify patients by viewing patient records, 3) how to securely transfer potential participant information to and from study personnel and medical staff, and 4) appropriate times to meet with medical staff regarding study recruitment. In addition, several physicians requested that they be able to inform potential participants about the study before any contact from study personnel.

To date, the MSSM site has enrolled 8 patients into the focus group phase of the project; FCCC has enrolled 3 patients. We collected both qualitative and quantitative data on all participants. All male participants had been diagnosed with a rising PSA. One woman (age 61) has been enrolled in the study. Male patients were on average 63.4 years old (SD: 5.8), 85.7% reported being retired, 42% are married and 42% are divorced, all participants completed high school and 57% had a college or post graduate degree. The minority population is 29%; 71% of patients are Caucasian/Non-Hispanic.

All questionnaire data have been entered in the SPSS database, however, statistical analyses have not been performed due to the small number of patients enrolled. The focus group data was transcribed and analyzed by the PI and research staff. Preliminary qualitative analysis from the focus group transcripts reveal several themes. Focus group participants, all of whom were initially treated with radical prostatectomy reported treatment regret.

For example several men stated that they “don’t know if they would have done it again” knowing what they know now and “wonder if radiation would have worked”.

All the focus group participants reported that they believe a rising PSA is a serious problem. They reported that while they were more “shocked” by the initial prostate cancer diagnosis, they believe that a rising PSA diagnosis threatens their survival. Participants reported that they believe having a rising PSA means that the surgery was not successful, and that the cancer might come back “I felt like the surgeon did not get everything, like one cancer cell got away… although I do not have a prostate there may be a cancerous cell.” Others expressed confusion, “I’d be sitting around thinking…how come this is happening? I was saddened by the rising PSA.” When asked about treatment goals, participants reported a desire to manage their rising PSAs and delay the progression of the disease. One man reported, “you just want to outlive the disease, because the end of the disease is not pleasant. You’d much rather get run over by a truck, I guess.”

Several of the focus group participants reported anxiety concerning their appointments with physicians saying that they have routine appointments but never know what has changed. One patient reported, “I come every three months and start to worry for about a month ahead.” Others reported that they may “freak out” or “get mopey” but they try to “do the best [they] can Another said, “I think about having cancer… and what I am going to do, it is always in the back of my head.”, and, “I worry about dying from prostate cancer… it’s always on my mind.” Others try to limit the time they think about their rising PSA, such as thinking about it only “one minute a month”.

Many participants reported that the diagnosis of a rising PSA prompted them to gather more information about prostate cancer and “do it right” with regard to treatment. Several men reported attending seminars and joining online organizations that distribute information about prostate cancer. One participant reported, “when he said the PSA was elevated then I realized I’m not totally cured. So that’s when I dug in and started to learn about [herbal therapies] and went to symposiums.” Most men reported receiving information about rising PSA from their doctors, although approximately 50% of men reported using the computer and the Internet as their primary information source. “I have gotten a lot of information from doctors. I would like more. I should know more.” Participants expressed confidence in their doctors and their professional opinions. They also recognized that “each fingerprint is different” and “there is no magic bullet” in concluding that treatments to not work the same for everybody. They believe that patients have a responsibility to learn as much as they can, “If a patient is cognizant, he has to manage his own care. He can’t just sit back and say ‘oh well the doctor didn’t tell me…’ Now, he’s got to be very, very careful.”

We performed an additional interview with the wife of one of our focus group participants, using a script adapted for the spouses and partners of rising PSA patients. Interviewing the partner of a patient with a rising PSA was extremely informative as we gained insight of the disease from a family perspective. The spouse expressed confusion about the rising PSA, “Now that his PSA is rising again it makes no sense to me.” She also stated that her husband is having a more difficult time dealing with his rising PSA than he may report. She said, “It’s all about men trying to keep everything in… it is demeaning for them to be sick.” She added, “He told me when I am not home he cries alone… he quit his job… says he is going to die anyways.”

Future Steps: The organizational difficulties at FCCC have been overcome and the FCCC site has initiated recruitment. However to complete the formative qualitative phase in a more expedient manner we will conduct individual interviews with patients and their spouses rather than trying to attempt to organize a focus group. From our experience patients and their spouses were more likely to participate in individual interviews than reconvening for a focus group. Too many patients were lost due to their refusal to participate in focus group sessions. Thus, we will be switching to individual interviews and have started to modify the focus group guide appropriately. Increased efforts will be made to enroll spouses into the qualitative and quantitative part of the study.

Key Research Accomplishments:

1) We have obtained IRB approval from MSSM and have also received Continuation Approval from MSSM and have been recruiting patients and their spouse/partners.

2) We have developed databases for MSSM and FCCC in SPSS for the questionnaires including the design of a coding scheme to link patients to their spouse/partner in the database

3) All data have been entered.

4) We have refined the focus group guide in collaboration with all investigators and collaborating physicians.

5) We have refined the spouse/partner focused questionnaire to better assess the spouses/partner's experience with a rising PSA.

6) Several in person meetings with physicians both at MSSM and FCCC were held to clarify recruitment procedures.

7) We have successfully completed one focus group a MSSM; including 7 patients and 1 spouse/partner. FCCC has enrolled 2 patients and 1spouse partner

6) FCCC has clarified recruitment procedures and has begun the recruitment process.

7) We have implemented monthly phone conferences with FCCC and monthly research meetings with the collaborating physicians from MSSM to monitor progress and better track eligible patients.

Reportable Outcomes: Not Applicable.

Conclusions: The initial delays in recruitment have prompted us to somewhat change the methodology. Rather than organizing focus groups which required patients to return to the study site, we will be completing individual but separate interviews with patients and spouses. This should greatly accelerate the completion of the first phase of this research project.

Appendices: NONE.

Supporting Data: NONE